HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: CFN 1118201

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

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01-BLT-24

March 23, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Theodore Pavlos, President
Jeppi Nut Company, Inc.
312 N. High Street
Baltimore, Maryland 21202

Dear Mr. Pavlos:

The Food and Drug Administration (FDA) conducted an inspection of your warehouse and nut manufacturing facility located at 312 N. High Street, Baltimore, Maryland, on February 8, 2001 through March 7, 2001. At the conclusion of the inspection, you were issued a Form FDA 483, Inspectional Observations (copy attached), which described the insanitary conditions present in your facility during the inspection. These conditions cause the food products manufactured and stored in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act).

The list of insanitary conditions observed by our investigators during the inspection includes:

- One live and 12 dead rodents in various locations throughout the facility.

- Examination of a lot consisting of 17/50 lb. bags of Rolled Oats revealed that 4 bags contained fluorescent stains. Three of the 4 fluorescent stained bags contained apparent rodent gnawed holes. Two of the 3 bags with the apparent rodent gnawed holes also contained at least 30 rodent excreta pellets inside the bags with the product. Approximately 100 rodent excreta pellets were on the floor adjacent to the lot.

- Examination of a lot consisting of 30 boxes of lollipops (49/3 oz. lollipops each) revealed that 2 boxes contained apparent rodent gnawed areas. Three lollipops in one of the boxes contained apparent rodent gnawing.

- Examination of a lot consisting of 6 boxes (24/10.6 oz. packages each) of Popcorn Supply Kits revealed 2 boxes with apparent rodent evidence. One of the 2 boxes contained an apparent rodent gnawed hole, fluorescent stains, and rodent excreta pellets on the box, and apparent rodent nesting material inside the box. The other box contained an apparent rodent gnawed hole and rodent excreta pellet at the opening of the gnawed hole.

- A lot consisting of 8 cartons (6/6 lb. 10oz. cans each) and 3 individual cans of cheddar cheese sauce contained fluorescent stains on the tops of 2 of the cans. There was apparent rodent nesting material and rodent excreta pellets inside 1 carton.

- A lot consisting of 59/50 lb. bags of Popcorn Kernels contained 9 bags with fluorescent stains, 1 bag with an apparent rodent gnawed area, and 4 rodent excreta pellets on or adjacent to the bags.

- A lot consisting of 8 cartons (6/5 lb. bags each) of caramel candies contained 1 carton with apparent rodent gnawing. One of the bags in the carton had an apparent rodent gnawed hole and 1 rodent excreta pellet on its exterior. Another bag had 5 rodent excreta pellets on its exterior.

- A lot consisting of approximately 600/50 lb. bags of shell peanuts contained 14 bags with fluorescent stains. Eight of the 14 bags contained apparent rodent gnawed holes. In some instances, the product itself bore fluorescent stains or apparent rodent gnawing.

- At least 771 rodent excreta pellets were observed on the floors in various locations throughout the facility (main and rear warehouses, restroom, retail display area, and the basement).

- Structural defects were observed in at least 6 locations in the facility (gaps under doors, holes in the walls) affording points of rodent entry and/or harborage. There was a leaking drainpipe in the basement.

- Manufacturing equipment, such as the nut roasters and popcorn machines, contained accumulations of dust, dirt, debris, and/or rust.

- Only 1 of the 2 restrooms was operable and neither had soap or other hand washing solutions available.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with the requirements of the Act and regulations. The specific violations noted in this letter and on the Form FDA 483 issued to you during the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

We are aware of your efforts, to date, to correct the cited deviations in conjunction with a written order from the Baltimore City Health Department and with the assistance of a private consultant. However, on the last day of our inspection, mice were still observed on glue boards in your facility. It is your responsibility to eliminate the apparent rodent infestation at your facility and to assure that further product adulteration does not occur.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 101 W. Broad Street, Falls Church, Virginia 22046-4200, to the attention of Gerald Miller, Compliance Officer. Mr. Miller can be reached at phone number 703/235-8440, extension 504.

Sincerely,

for Lee Bowers
Director, Baltimore District

Enclosure

cc: Mr. Bernard Bochenek
Director, Environmental Health
City of Baltimore
Department of Health
210 Guilford Avenue
Baltimore, Maryland 21202